PATENT COOPERATION TREATY

PCT

REC'D 30 OCT 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference PF-0612-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/23317	International filing date *(day/month/year)* 06 OCTOBER 1999	Priority date *(day/month/year)* 06 OCTOBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant INCYTE PHARMACEUTICALS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05 MAY 2000	27 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROBERT LANDSMAN Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/23317

I. Basis of the report

1. With regard to the **elements** of the international application: *

[X] the international application as originally filed

[X] the description:
pages 1-55, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the claims:
pages 56-57, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the drawings:
pages 1-7, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the sequence listing part of the description:
pages 1-18, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language ____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE
[X] the claims, Nos. NONE
[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/23317

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 17, 18, 20

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17, 18, 20 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-2, 7-11, 16, 19	YES
	Claims	3-6, 12-15	NO
Inventive Step (IS)	Claims	1-2, 7-11, 16, 19	YES
	Claims	3-6, 12-15	NO
Industrial Applicability (IA)	Claims	1-16, 19	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 3-6 lack novelty under PCT Article 33(2) as being anticipated by Fujiwara et al. (Database EMEST30, Accession No. C17798). The claims recite an isolated and purified polynucleotide encoding a fragment of the polypeptide of SEQ ID NO:1 and a complement thereof and a fragment which is at least 70% identical to the claimed fragment. The claims also recite a polynucleotide which hybridizes under stringent conditions to the claimed polynucleotide. Fujiwara et al. teach a polynucleotide which is 99.8% identical to a 556 base pair segment of SEQ ID NO:9. This polynucleotide would encode a fragment of SEQ ID NO:1 and would be expected to hybridize to the claimed polynucleotide. One of ordinary skill in the art would immediately envision the complement of the polynucleotide of Fujiwara et al.

Claims 1-2, 7-16 and 19 possess novelty under PCT Article 33(2) since no prior art reference discloses specifically a polypeptide comprising SEQ ID NO:1 or a fragment thereof, or a polypeptide which is at least 90% identical to SEQ ID NO:1. These claims do not teach the full-length polynucleotides of the claims, vectors, host cells, proteins, antibodies, or the claimed methods.

Claims 3-6 and 12-15 lack an inventive step under PCT Article 33(3) as being obvious over Fujiwara et al. in view of Sambrook et al.

The claims recite an isolated and purified polynucleotide encoding a fragment of the polypeptide of SEQ ID NO:1 and a complement thereof and a fragment which is at least 70% identical to the claimed fragment. The claims also recite a polynucleotide which hybridizes under stringent conditions to the claimed polynucleotide. Fujiwara et al. teach a polynucleotide which is 99.8% identical to a 556 base pair segment of SEQ ID NO:9. This polynucleotide would encode a fragment of SEQ ID NO:1 and would be expected to hybridize to the claimed polynucleotide. One of ordinary skill in the art would immediately envision the complement of the polynucleotide of Fujiwara et al.

Fujiwara et al. do not teach a vector, host cell, a method for making the protein, or a pharmaceutical composition. However, Sambrook et al. do teach vectors, host cells, methods of making (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7):C12P 21/06, 21/04; C12N 1/20, 15/00, 15/09, 15/63, 15/70, 15/74; A01N 37/18; A61K 38/00; C07K 1/00, 2/00, 4/00, 5/00, 7/00, 14/00, 16/00, 17/00 and US Cl.:435/69.1, 70.1, 71.1, 71.2, 252.3, 320.1, 325, 471; 514/2; 530/300, 350; 536/23.5

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
proteins and pharmaceutical compositions such as water or buffer used in the amplification and purification process. It would have been obvious to one of ordinary skill in the art to have substituted the polynucleotide of Fujiwara et al. for the polynucleotide in the polycloning region of Sambrook et al. for the purpose of transfecting a host cell to produce the protein in order to characterize the protein. There would have been a reasonable expectation of success for one of ordinary skill in the art to have performed this procedure since these techniques were widely used and highly successful at the time of the invention.

Claims 1-2, 7-11, 16 and 19 possess an inventive step under PCT Article 33(3) since no prior art reference fairly suggests the claimed proteins, polynucleotides, fragments, antibodies, or methods.

Claims 1-16 and 19 possess industrial applicability under PCT Article 33(4), because the molecules and methods which are taught by the description encompassed by the claims can be utilized in the field for which they were intended.

---------- NEW CITATIONS ----------

SAMBROOK et al. Molecular Cloning: A Laboratory Manual. second edition. Cold Spring Harbor Laboratory Press. 1989. pages 17.2 - 17.11 and 17.42 - 17.44.